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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/655,093

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Yutaka Umehara

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10/19/2007

DAVIS WRIGHT TREMAINE LLP/Los Angeles

865 FIGUEROA STREET

SUITE 2400

LOS ANGELES, CA 90017-2566

EXAMINER

WARE, DEBORAH K

ART UNIT

PAPER NUMBER

1651

MAIL DATE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/655,093	UMEHARA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Deborah K. Ware	1651	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 August 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 4,7,8,10-13,20,22-24 and 27-30 is/are pending in the application.
- 4a) Of the above claim(s) 4,7,8,10-13,20,22 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23-24 and 27, 29-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date. _____                                                         | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 4, 7-8, 10-13, 20, 22-24 and 27-30 are presented for reconsideration on the merits.

#### ***Response to Amendments***

The amendments filed August 1, 2007, and April 18, 2007, have been received and entered. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Election/Restrictions***

Applicant's election with traverse of Group I, claims 1, 3 and 23-27, in the reply filed on September 21, 2006, is acknowledged. However, claims 1 and 3 have been canceled and new claims 29-30 have been added of which are drawn to the elected subject matter. The traversal of record is on the ground(s) that the restriction is improper because a serious burden has not been established. This is not found persuasive because the Examiner is forced to search all of the newly claimed inventions which require additional steps in their separate and distinct processes not required before and that the art as previously applied may not be applied against the newly amended claimed subject matter and added new claims upon filing of the RCE. Different classifications have subdivided the previously claimed inventions based upon the amendments in accordance with the filing of a RCE. These new classifications and amendments lead the Examiner to perform another exhaustive and continuing search of differently claimed subject matter and hence a serious burden of search is the result.

However, as indicated below claims can be rejoined at the time of indication of allowable subject matter:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claims 23-24 and 27-30 are reconsidered on the merits. Although the amendments to non-elected claims is noted but now allowable subject matter has been indicated.

Therefore, the requirement is still deemed proper and is therefore made FINAL.

Claims 4, 7-8, 10-18, 20, 22 and 28 are hereby withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 21, 2006.

#### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on February 28, 2005, was filed after the mailing date of the first office action on December 14, 2004. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

#### ***Response to Amendment***

The amendment and extension of time filed therewith on April 18, 2007, have been received and entered. The remarks filed August 1, 2007, have also been entered of record and will be considered herein. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Response to Arguments***

Applicant's arguments filed December 12, 2005, have been fully considered but they are not persuasive. The argument that the whole segment is required by the claims is noted, however, Applicants claims actually require a *portion* (emphasis added) of a whole tissue, which reads on an intestinal segment tissue as disclosed by Badylak et al. Applicants' own specification at page 5, lines 14-17, define the term "whole" to denote that the biological materials are not decellularized or digested prior to being processed into a cell support matrix. While Applicants have amended the instant claims to include full and intact organs or a portion thereof, the whole teaching of the specification clearly describes that a full and intact organ is not necessarily processed. Also the claims clearly require a portion (emphasis added) as discussed above.

The second argument with respect to the number of layers is noted, however, the art has been applied on the basis of tissue powder and not layers, per se. Thus, the argument(s) are not deemed persuasive. In addition, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., Applicants' definition of "portion" in the claims is not described in the claims per se) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Thus, the argument that Badylak is not using the entire segment is noted, but not persuasive.

The cited disclosure clearly teaches that the intestine segment used to prepare the disclosed cell matrix composition does not have to be digested and is comminuted by tearing, cutting, grinding, shearing and the like, note column 2, lines 52-53. Furthermore, the open ended term "comprising" does not necessarily omit a tissue powder derived from intestinal segment as disclosed by Badylak et al. The "whole segment" for which Applicants argue as the claimed critical feature for their invention is clearly anticipated by Badylak et al teachings of their cell culture matrix derived from the intestinal submucosa comprising a segment of intestinal tissue, see the abstract, line 9. For these reasons and those of record Applicants' arguments are not deemed persuasive and the rejection is sustained.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23, 27 and 29-30 are rejected under 35 U.S.C. 102(a)/103 as being anticipated by newly cited Yang, or in the alternative as obvious over the cited reference, Yang, see enclosed PTO-1449 Form.

Claims are drawn to cell culture matrix composition comprising tissue powder and method for producing the tissue powder.

Yang teaches cell culture matrix composition comprising tissue powder and method for producing the tissue powder, see abstract and page 2, column 2, [0033], line 3, page 3, [0045], lines 1-30, page 6, [0084], line 5, page 7, [0087], all lines. A medium is also disclosed.

The claims are identical to the cited disclosure of Yang and are considered to be anticipated by these teachings therein. Yang clearly teach a segment of blood vessel from which a powder is derived as the tissue composition. In the alternative that sonication can be shown not to be used by Yang, since the term is silent, but Yang does teach that any form of alternative means can be carried out, note page 7, column 1, last full paragraph, the selection of sonication is deemed an obvious choice by one of skill in the art because it is a well known technique in the art. Therefore, in the alternative the claims are rendered obvious over the cited prior art.

### ***Response to Arguments***

Applicant's arguments filed April 18, 2007, have been fully considered but they are not persuasive. The argument that each and every element is required is noted. However, each and every element has been provided by Yang since blood vessels are



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disclosed and Yang discloses many ways in which the tissue can be prepared and treated. Yang teaches the desire in the art to grind and ground up the whole tissue. These blood vessels may be construed as whole tissue. The second argument with respect to "many or all of the essential elements" will be included by selecting the whole organ is noted, however, the art does read on whole tissue and does at least suggest using whole tissue. Thus, the argument(s) are not deemed persuasive. For these reasons and those discussed above the rejection is sustained. Also it should be noted that Applicants have not provided any evidence that all or some of the essential elements are contained within the claimed tissue powder and it is, therefore, considered to be no different than what is disclosed in the cited prior art.

### ***Claim Rejections - 35 USC § 103***

Claims 23-24, 27 and 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Badylak et al, Yang as cited above, Weiss et al and Vail et al, all cited of record, for reasons set forth in prior action of December 14, 2004, see pages 6-7 and Yang is discussed above and Badylak et al discussed below.

Claims and Yang are discussed above.

Badylak et al (US Patent No. 5,516,533) teach Badylak et al, cited above, teach a cell culture matrix composition comprising a tissue powder derived from an intestinal segment and the composition may further comprise a medium. Note column 2, lines 45-61. The disclosed medium is water or buffered saline which may be optionally added to the composition.

### ***Response to Arguments***

Applicant's arguments filed April 18, 2007, have been fully considered but they are not persuasive. The argument that Badylak et al do not teach or suggest the newly amended claims is noted. However, as discussed above, the intestinal tissue disclosed by Badylak et al is not less than a portion, and even if one of skill can optionally read and interpret the cited disclosure as Applicants have, then within the meaning of Applicants' own definition of "whole" as discussed above one of skill would have been motivated to use a portion of intestinal tissue as disclosed by Badylak et al because the reference teaches that the powder is obtained without digestion of the tissue. All that the compositions require is tissue powder, and the prior art teaches this. Also wherein Badylak et al is lacking concerning sonication the other secondary reference clearly provide the remedy for this proposed insufficiency of Badylak et al.

Sonication is clearly disclosed by the cited prior art secondary references and one of skill would have been motivated to use these techniques to provide for the powder form of the organ because they are disclosed to be useful for the preparation of similar products as claimed herein. The argument that combination of references is improper is noted, however, each reference is applied to show the level of techniques (i.e. sonication) which are available to those of skill in the art. Fine tissue powder can be prepared by sonication and one of skill would have known this at the time the claimed invention was made. Thus each of the claim features are either disclosed or are at least suggested or intrinsic to the teachings of the cited prior art.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-1449. Therefore, the claims are properly rejected.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Deborah K. Ware  
October 13, 2007



DAVID M. NAFF  
PRIMARY EXAMINER  
ART UNIT 128/657